UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 13 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Expedited Risk Analysis for OMAS Oil-Filled Radiator Heaters

FROM: Charles L. Elkins, Director
Office of Toxic Substances (TS 792)

TO: A. E. Conroy, Director
Office of Compliance Monitoring (EN 342)

This memo responds to your April 1 request for an expedited risk assessment for OMAS oil-filled electric radiator heaters. In order to save time, the approach used in estimating exposure and calculating risks for exposure to PCBs from these heaters is the same approach used for the calculation of exposure and risk estimates for DeLonghi oil-filled radiator heaters. The similarities of design, performance and potential for exposure to PCBs from leaks or spills were outlined in my April 27 memo to the TSCA Regional Branch Chiefs on exposure assessments and risk calculations for DeLonghi heaters (copy attached).

The estimates of exposure and calculation of risks for OMAS units, while using the identical exposure scenarios as those used for DeLonghi units, are based on a PCB level of 1400 ppm Aroclor 1254, which is the highest concentration reported for the 14 OMAS units sampled and analyzed. The description of each scenario, route of exposure, annual exposure, and LADD calculated for each exposure are listed on the attached chart. The estimates of exposure and calculation of risk for each of the scenarios are outlined below.

A. Exposure Assessments

Scenario 1: The Slow Leak

For the period prior to leak discovery, OTS estimated inhalation exposures occurring for 8 hours per day for 5 days prior to discovery of the leak. The likely human exposure from this leak is 6.95×10^{-2} mg PCBs over a 5-day period. The corresponding LADD (for purposes of lifetime cancer risk assessment) is 3.8×10^{-8} mg/kg/day.

For dermal exposures during the cleanup of spilled oil, OTS assumed that the surface area of both hands were covered with contaminated mineral oil and that 100% of the PCBs in the oil are absorbed. The likely human exposure from this event is 15.38 mg PCBs over a period of 1 day. The corresponding LADD is 8.38 x 10^{-6} mg/kg/day.

For inhalation exposures from residual contamination during the period of evaporation of PCBs following cleanup of leaked oil, OTS calculated exposure 2.31 x 10^{-2} mg/year (318 days). This assumes that the cleanup is less than thorough, and that the residual PCBs evaporate over a period of 318 days. The corresponding LADD is 1.26 x 10^{-8} mg/kg/day.

The total LADD corresponding to the exposure for the slow leak scenario for inhalation exposure prior to leak discovery, dermal exposure during cleanup, and inhalation exposure from residual contamination is calculated at 8.4 x 10^{-6} mg/kg/day.

Scenario 2: The Large Leak

For exposures during cleanup of leaked oil, OTS assumed that the entire contents of the heater leaked (approximately 3 liters of oil, 3.65 grams PCBs based on contamination at 1400 ppm), that the area of both hands was covered with oil, and that 100% of the PCBs in the oil was absorbed.

OTS calculated inhalation exposure for this event at 1.69 x 10^{-2} mg/year. The corresponding LADD for this exposure is 9.22 x 10^{-9} mg/kg/day.

For dermal exposure during cleanup of leaked oil, OTS calculated exposure at 15.38 mg occurring during a period of 1 day. The corresponding LADD is 8.38 x 10^{-6} mg/kg/day.

For inhalation exposures during the period of evaporation of PCBs following cleanup of leaked oil, OTS calculated exposures at 1.48 mg/year (318 days). The corresponding LADD is 8.1 x 10^{-7} mg/kg/day.

The total LADD corresponding to the large leak scenario from inhalation and dermal exposures is calculated at 9.2 x 10^{-6} mg/kg/day.

Scenario 3: The Spraying Leak

For dermal exposure to contaminated oil during its release from the radiator, OTS calculated exposure at 7.74 mg PCBs, occurring during a single event of short duration. The corresponding LADD is 4.22 x 10^{-6} mg/kg/day.

For dermal exposure during cleanup of the leaked oil, OTS calculated exposure at 15.38 mg PCBs, occurring over a period of 1 day. The corresponding LADD is 8.38 x 10^{-6} mg/kg/day.

For inhalation exposure during the period of evaporation of PCBs from cleanable surfaces, OTS calculated exposure at 4.04 x 10^{-2} mg/year (318 days). The corresponding LADD is 2.2 x 10^{-8} mg/kg/day.

For inhalation exposures during the period of evaporation of PCBs from non-cleanable surfaces, OTS calculated exposure at 3.65 mg/year. The corresponding LADD is 2.03 x 10^{-6} mg/kg/day.

For dermal exposure from contact with non-cleanable surfaces, OTS calculated annual exposure at 2.64 mg/year. The corresponding LADD for this exposure is 1.01 x 10^{-4} mg/kg/day.

The total LADD corresponding to the exposure for the spraying leak scenario for direct dermal exposure to sprayed material, dermal exposures during cleanup inhalation exposures from residual material and dermal exposures from non-cleanable surfaces is calculated at 1.1 x 10^{-4} mg/kg/day.

B . <u>Risk Estimates</u>

(1) Individual:

(a) <u>Acute</u>: The LD (50) for PCBs (in laboratory animals) ranges between 1295 and 11,300 mg/kg/bw. The highest calculated acute exposure for continued use of the OMAS heaters (based on a PCB level of 1400 ppm) is 15.38 mg PCBs. Based on laboratory animal data, human exposures to 15.38 mg of PCBs would not pose an acute hazard.

(b) <u>Subchronic</u>: To determine risk for non-carcinogens (or to determine risk for effects other than carcinogenesis), acceptable daily intake (ADI) rates are calculated. An ADI is the amount of a chemical substance that is not expected to result in any adverse effect after long term (usually lifetime) exposure to humans. As outlined in the attached memo, the ADI value for PCBs should not be compared to the exposure values calculated for single event exposures for leaking heaters, since this ADI value is intended primarily for use in calculating the amount of a chemical which is not expected to result in adverse effects after long-term exposure.

(c) Oncogenic: To determine the oncogenic risk associated with the continued use of OMAS heaters, one multiplies the potency estimator (q_1*) for PCBs by the LADD. The potency estimator for PCBs has been estimated as ranging from 3.4 mg/kg/day^{-1} to 7.7 mg/kg/day^{-1}. The highest estimated LADD from the continued use of OMAS heaters is 1.1 x 10^{-4} mg/kg/day for persons exposed during a spraying leak event. An LADD of 1.1 x 10^{-4} results in a corresponding estimate of oncogenic risk ranging from 4.1 x 10^{-4} to 9.2 x 10^{-4}.

(d) Excess cancer risk: In the absence of reliable estimates of frequency of leaks/spills from OMAS heaters, OTS has assumed the leakage or spillage frequency to be approximately the same as that reported for the DeLonghi heaters, since the two brands are of similar design, construction and performance. In the DeLonghi risk assessment, the number of heaters actually experiencing leaks or spills were calculated at .13% of the total number of units in use (1960 out of 1.5 million). In order to be conservative, OTS assumed that all leaks reported are spraying leaks (with highest calculated estimates of exposure), and that all leaking units contained the maximum reported concentration (1400 ppm level of PCB contamination).

Assuming that .13% of the 52,000 OMAS units imported into the U.S. in 1985 experienced leaks or spills, a total of 68 units would be involved. Based on sampling results from OMAS units tested thus far, OTS expects that 78.6% of these leaking units are contaminated, and OTS assumes, as a worst case, that these units spill by spraying PCBs. OTS therefore expects a maximum of 53 persons to be exposed to PCBs from use of OMAS heaters. Assuming worst case exposures and using the available estimates of oncogenic risk, (4.1 x 10^{-4} to 9.2 x 10^{-4}), OTS estimates .02 to .05 excess cancers due to the continued use of OMAS heaters.

C. Costs of Recall and Disposal

The following example is calculated for all OMAS units imported into the U.S. in 1985 (52,000):

Assume all units imported in 1985 were recalled:

\$20/per	Value of individual unit
\$50/per	Cost of recall (notification and collection)
\$35/per	Cost of disposal
= \$105	(per unit x 52,000 units = \$5,460,000 to avoid .05 excess cancers).

D. Disposal Considerations

Assuming a volume of .008 lbs PCBs per OMAS unit, with 52,000 units imported and distributed in 1985, the total PCBs for all OMAS units sold in 1985 would be 416 lbs. PCBs. The cost of disposal of all 52,000 units sold in 1985 can be estimated using 35 lbs. as the average weight of one unit, with \$1.00 per pound the average cost of PCB disposal by incineration. Thus, the total estimated cost for disposal of 52,000 units at 35 lbs./unit at a cost of \$1.00/lb. would be \$1,820,000 to dispose of 416 lbs. PCBs. This estimate does not include the costs of shipment for disposal, which depending on carrier used, range from \$7.17 to \$21.80 per 35 lb. unit within a shipping radius of 300-500 miles. Testing costs to sample and analyse individual units for PCB contamination currently exceed \$75.00 per unit, over twice the cost of disposal.

Attachment

APR 27 1987

MEMORANDUM

SUBJECT: OTS Response to Regional Concerns in DeLonghi Heater Exposure Assessment and Risk Estimates

FROM: Charles L. Elkins, Director
Office of Toxic Substances (TS-792)

John J. Neylan, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

TO: All USEPA Regional TSCA Branch Chiefs

This memorandum responds to comments contained in the January 23, 1987 memo from Anita Frankel (Region X) to John Neylan (USEPA Headquarters), and the February 18, 1987 memo from William H. Sanders (Region V) to Denise Keehner (USEPA Headquarters). The Region X memo (attached) requested discussion and clarification of 7 topics relating to the information contained in the press release and exposure and risk estimates for DeLonghi brand oil-filled radiator heaters. Unit II below addresses item 1 of these 7 topics, the recalculation of the exposure and risk assessment. Item 2 and Item 3 (options to Item 1) of the Region X memo are omitted because OTS has calculated the exposure assessment as requesed in Item 1. In addition, Unit II below presents an analysis of these risks, the benefits of the continued use of these heaters, and the costs associated with the regulatory measures necessary to reduce these risks. Unit III addresses items 4 through 7 of the Region X memo, as well as specific comments relative to the press release which are discussed in this memo.

I. Background

DeLonghi America imported approximately 1.5-2.5 million oil-filled electric radiator heaters into the U.S. in the period 1980-1986. EPA testing of 33 DeLonghi units which were imported into the U.S. in 1985 revealed that 15 of 33 units tested contained Aroclor 1254/1260 at levels of 5 ppm or greater.

Three of the 15 contaminated units exceeded 200 ppm, with the majority of the remaining units showing Aroclor 1254/1260 levels between 5 and 180 ppm. The highest level detected was 420 ppm (the 900 ppm level cited in the Region X memo has never been substantiated to our satisfaction; we have requested from Canadian sources a copy of the analysis performed and the method used on several occasions without success).

Each of these heaters contains approximately 2610 grams of mineral oil and, where PCBs are present, approximately .01 grams PCBs (for heaters containing 5 ppm PCBs) to 1.09 grams PCBs (for heaters containing 420 ppm PCBs).

II. Regulatory Review of Continued Use of DeLonghi Heaters.

A. Exposures.

Although DeLonghi heaters are manufactured in a manner which minimizes the likelihood of oil leaks and spills, the principal route of PCB exposure to the consumer would theoretically result from three basic types of leaks and spills:

- the slow leak that goes largely undetected until enough oil has spilled out making the leak obvious;
- the "large" leak that empties the entire contents of the oil reservoir in the unit in a comparatively short period of time; and,
- the pressurized leak that results in the release of oil in a spray-like dispersion.

For each of these spill scenarios, assuming a worst case PCB concentration of 420 ppm, OTS calculated the following conservatively high expected exposures.

1. The Slow Leak.

For scenario 1, OTS estimated exposures during:

(a) the period prior to leak discovery;

(b) the period during spill cleanup; and,

(c) the period following cleanup (exposures to residual PCBs).

For the period prior to leak discovery, OTS estimated that inhalation exposures would occur for 8 hours per day for 5 days prior to discovery of the spill (and subsequent cleanup). The likely human exposure from such a leak is 2.93×10^{-5} mg PCBs over a 5 day period (this assumes that mineral oil retards the volatilization of PCBs, which is likely). The corresponding lifetime average daily dose (LADD) (for purposes of cancer risk assessment) is 1.6×10^{-11} mg/kg/day.

For dermal exposures during the cleanup of spilled oil, OTS assumed that the surface area of both hands were covered with contaminated mineral oil and that 100% of the PCBs in the oil are absorbed, The likely human exposure from such a cleanup effort is 4.6 mg PCBs over a period of 1 day. The corresponding LADD for this event is 2.51×10^{-6} mg/kg/day.

For inhalation exposure from residual contamination, OTS assumed less than thorough cleanup, and that the act of cleaning up the spill with paper towels could spread the PCBs. OTS assumed that the residual PCBs would evaporate over a period of 318 days. The likely human exposure for this event from the volatilization of the residual PCBs is 3.8×10^{-3} mg over a period of 318 days, which corresponds to an LADD of 3.1×10^{-9} mg/kg/day.

The total LADD corresponding to the exposure for the slow leak scenario for inhalation exposure prior to leak discovery, dermal exposure during cleanup, and inhalation exposure from residual contamination is calculated at 2.5×10^{-6} mg/kg/day.

2. <u>The Large Leak</u>.

OTS estimated human exposures from a large leak:

(a) during cleanup; and,

(b) following cleanup (from evaporation of residuals).

For exposures during cleanup, OTS assumed both inhalation and dermal exposures. OTS assumed that the entire contents of the oil reservoir of the heater leaked (approximately 3 liters of oil; 1.09 grams of PCBs), that the area of both hands was covered with oil, and that 100% of the PCBs in the oil was absorbed. The likely human exposure from this event is approximately 4.61 mg PCBs over a 1 day period. The corresponding LADD for this event is 2.51×10^{-6} mg/kg/day.

For exposures (to residual PCBs) following cleanup efforts, OTS assumed a less than thorough cleanup and that "cleanup" would actually spread residual PCBs. The likely human exposure from the volatilization of residual PCBs during such an event is 2.4×10^{-1} mg over a 318 day period, or .0007 mg/day. The corresponding LADD is 1.95×10^{-7} mg/kg/day.

The total LADD corresponding to the exposure for the large leak from dermal exposure during cleanup and inhalation exposure following cleanup from evaporation of residues is calculated at 2.7×10^{-6} mg/kg/day.

3. The Spraying Leak.

OTS estimated human exposures from a spraying leak assuming:

(a) direct exposure to the sprayed material;

(b) dermal exposure during cleanup;

(c) inhalation exposure from residual material; and,

(d) dermal exposure from non-cleanable surfaces.

For exposures during a spraying leak, OTS assumed that the area equal to the area of one hand became covered with contaminated oil. The estimated human exposure for this event is 2.32 mg PCBs. The corresponding LADD for this event is 1.26 x 10^{-6} mg/kg/day.

For dermal exposures during cleanup, OTS assumed the area of both hands were covered with oil, and that 100% of the PCBs in the oil were absorbed. The estimated human exposure for this event is 4.61 mg PCBs. The corresponding LADD for this event is estimated to be 2.51 x 10^{-6} mg/kg/day.

For subsequent exposure to residual PCBs after a spraying type event, OTS estimated both inhalation and dermal exposures. The estimated human exposure for this event is 0.200 mg, or .0006 mg/day. The corresponding LADD for this event is 3.0 x 10^{-5} mg/kg/day.

The total LADD corresponding to the exposure for the spraying leak scenario for direct dermal exposure to sprayed material, dermal exposures during cleanup, inhalation exposures from residual material and dermal exposures from non-cleanable surfaces is calculated at 3.4 x 10^{-5} mg/kg/day.

B. Risk Estimates.

(1) Acute: The LD (50) for PCBs in laboratory animals ranges between 1295 mg/kg/bw and 11,300 mg/kg/bw. The highest estimated acute exposure for the continued use of DeLonghi brand heaters is approximately 6.93 mg of PCBs, occurring during a spraying leak event. Based on laboratory animal data, human exposures to 6.93 mg of PCBs would not present an acute hazard.

(2) Subchronic: To determine acceptable risk for non-carcinogens (or to determine acceptable risk for effects other than carcinogenesis), acceptable daily intake (ADI) rates are calculated. An ADI is the amount of a chemical substance that is not expected to result in any adverse effect after long-term (usually lifetime) exposure to humans. An ADI is determined by

dividing the no observable effect level (NOEL) by an uncertainty factor. OHEA has suggested an uncertainty factor of 100 for PCBs in combination with an NOEL of 1.0 mg/kg/day. Thus, the ADI for PCBs is 0.7 mg/day for adults (1.0 mg/kg/day x 70 kg/bw = 70 divided by the uncertainty factor of 100 = 0.7). The highest estimated long-term human exposure to PCBs from the continued use of DeLonghi heaters is less than 0.200 mg/kg/day, which is below the ADI.

Because the ADI is a value which is calculated to determine the amount of a chemical which is not expected to result in adverse effects after long-term exposure, the ADI value should not be compared with the values calculated for exposures to chemicals which occur only in a single day. Comparing the ADI for PCBs with the single event exposure values calculated in the exposure scenarios outlined above for leaking heaters (e.g., 4.6 mg PCBs in one day) is not appropriate.

(3) Oncogenic: To determine oncogenic risk associated with the continued use of DeLonghi brand heaters, one multiplies the q_1* (potency estimator) for PCBs by the LADD. The q_1* for PCBs has been estimated as ranging from 3.6 mg/kg/day^{-1} to 7.7 mg/kg/day^{-1} . The highest estimated LADD from the continued use of DeLonghi heaters is 3.4 x 10^{-5} mg/kg/day for persons exposed to PCBs during a spraying leak event. An LADD of 3.4 x 10^{-5} results in a corresponding lifetime oncogenic risk of 1.2 x 10^{-4} to 2.6 x 10^{-4} (assumes 1 person exposed for each leak/spill event).

(4) Excess cancer risk: DeLonghi's estimate of the frequency of leaks/spills from their heaters suggests that 196 out of 1.5 to 2.5 million units reported leakage or spillage of oil during the period 1983-1986. In order to be conservative, OTS has made the following worst case exposure assumptions:

- That the rate of leaking units is one order of magnitude higher than reported (1960 vs. 196);
- that all leaks reported are spraying leaks (with highest calculated estimates of exposure); and,
- that all leaking units contain the maximum reported concentration (420 ppm level of PCB contamination).

Assuming that 1960 out of 1.5 million units actually experience leaks or spills, this represents 0.13% of the units in use. Based on sampling, OTS expects that 45% of the leaking units are contaminated, and spill by spraying PCBs. OTS therefore expects a maximum of 882 persons to be exposed to PCBs from use of DeLonghi heaters. Assuming worst case exposures and using the two available estimates of oncogenic risk, (1.2×10^{-4} and 2.6×10^{-4}), OTS estimates .10 to .23 excess cancers due to continued use of DeLonghi heaters. More reasonable assumptions regarding the PCB concentrations in these heaters (i.e., concentrations in the 5-180 ppm range rather than the 420 ppm concentration used in the quantitative estimate) and the type of spill (i.e., a slow or large leak versus a pressurized spray dispersion) would yield much lower estimates of excess cancers.

C. Benefits of Continued Use of DeLonghi Heaters.

The auxilliary home heater market has existed since at least the 1950's, but portable electric space heaters have only recently gained in popularity due to economic and environmental considerations. The oil-filled radiator heater, popular in Europe for years, has only recently become popular in the U.S.

The first oil-filled heaters were imported from Europe for sale in the U.S. early in 1980 and, with the exception of one oil-filled baseboard model (Embassy brand), continue to be produced exclusively in Europe.

Even though oil-filled electric space heaters have only been available in the U.S. since 1980, the market has expanded rapidly. Almost 1 million units were sold in 1985 alone. With the accelerated sales of these units over this comparatively short time period, the cost to the consumer has decreased significantly. At the time of first importation into this country, DeLonghi oil-filled radiator type units typically sold for as high as $150 at retail. Current market prices for these same DeLonghi units is now around $40 at retail. Thus, the low cost factor to the consumer of this type heater in comparison to the other available types (kerosene, propane, quartz element, etc.) is a definite advantage.

Portable space heaters of all types have always had safety hazards associated with them, including burns, fire, or electrical shock. While electrical space heaters with open or ribbon elements are more likely to cause fires and shock than those with closed elements or oil-filled reservoirs, both open and closed types can cause contact burns. The kerosene heater is another type of heater that poses a distinct threat of burns, along with the possibility of a fire from the unit itself or as a consequence of the usual hazards associated with handling and storing a flammable liquid fuel. Additionally, a significant health hazard may be present during the operation of kerosene heater from the noxious gases produced during their operation. The levels of these gases may reach unacceptable levels, even in a well-ventilated room.

In general, the convection-only type electric space heaters (of which DeLonghi is one) pose significantly less hazard that the other types of heaters with respect to fire and electrical shock, although they too may become hot during operation, and can cause contact burns. (The external surface of the fins on the DeLonghi radiator-type heaters routinely reach contact temperatures of approx. 140^0 C).

Taking into consideration the safety precautions necessary for safe use of portable electric space heaters, the DeLonghi type oil-filled electric radiator heater are distinctly preferable to the liquid (kerosene) or compressed gas (propane) type heaters, both in cost of initial purchase and operation, as well as in safety of operation.

D. Costs of Recall and Disposal.

The following example is calculated for DeLonghi units purchased within a specific time period as a general estimate of the overall cost of a recall action:

Assume all units purchased in 1983-1986 were recalled:

\$20/per	Value of individual unit
\$50/per	Cost of recall (notification and collection)
\$35/per	Cost of disposal

= \$105/per unit x 1.5 million units = \$157 million, plus an additional estimated disposal cost (see next section) to a total of approximately \$628 million to avoid 1 excess cancer.

E. Disposal Considerations.

A chief concern expressed in the Region X memo addresses the recommendations for disposal of DeLonghi units as outlined in the press release. In the July 8, 1986 memo from Edwin Tinsworth to A.E. Conroy regarding the risk estimates and OTS recommendations for disposal of contaminated DeLonghi units, OTS drew the analogy between the large number of DeLonghi units in commerce, the low (.0001 lbs/unit) theoretical PCB content of these units, and EPA's prior decision regarding small PCB capacitor disposal, contained in the proposed rule for the use of PCBs in electrical equipment (see 47 FR 17436-7, April 22, 1982).

The estimated number of small PCB capacitors was very large; on the order of 500 million units. These capacitors contained between 0.1 and 0.6 lbs. PCBs per unit. Assuming an average PCB content of 0.35 lbs. per small capacitor, the total volume of PCBs contained in all small capacitors in service at that time would be approx. 175 million lbs. PCBs. By comparison, assuming a volume of .0001 lbs. PCBs per DeLonghi unit, along with the suggested total number of 2,500,000 units in commerce at this time, the total amount of PCBs for all units would be approximately 250 lbs. Another comparison is that 3500 heaters would have the same PCB content as one average small capacitor. Assuming that 1,500,000 of these units actually experience leaks or spills, the cost of disposal by incineration may be estimated, using an average weight per unit of 35 lbs., with $1.00 as the current average cost per pound of PCB disposal by incineration. The total estimated cost for 1,500,000 units weighing an average of 35 lbs. each at $1.00 per lb. would be $52,500,000 to dispose of 250 lbs. PCBs. This estimate does not include the costs of shipment for disposal which, depending on carrier used, range from $7.17 to $21.80 per unit (cost calculated for a 35 lb. unit within a shipping radius of 300-500 miles). (Although fewer than 1.5 million units actually contain PCBs, the test costs associated with determining whether in fact any individual unit contained PCBs would exceed $75 per unit. This is over twice the cost of disposal per unit).

As further outlined in the above referenced memo, because of the widespread use of these heaters, and the very low potential amount of PCBs per unit, OTS found, as in the case of small PCB capacitors, no cost-effective regulatory alternative targeted at controlling releases of the relatively small amount of PCBs which might occur as a result of the use of these heaters. Consequently, OTS has likewise not identified a reasonably cost-effective regulatory alternative that would result in significantly reducing the risks associated with potential release of the small amount of PCBs which may be contained in these heaters.

While the above referenced memo considered disposal methods for heaters within the scope of the immediate situation at the time (anticipated public reaction, logistics of a recall action, etc.), the intent of the OTS disposal recommendations to OCM were certainly not oriented towards directing the public to violate the PCB disposal requirements of TSCA. In fact, in an attempt to balance the letter and intent of the law as written under TSCA, the disposal recommendations made to OCM by OTS were intended to approach the issue of disposal on a more "real world" basis. As outlined in the Region X memo, OTS also "doubts that very many would report the failing of a defective, relatively low-priced appliance (especially after the warranty period had expired)." OTS would not expect a high degree of concern on the part of a consumer owning a non-leaking unit (in comparison with a person who detects a leak in their unit), provided that the information supplied to the consumer regarding the nature, amount and relative risk associated with handling of potentially contaminated heaters is presented in a manner consistent with "real world" situations. OTS therefore recommends that any follow-up notification or information made available to the public regarding the disposal of non-leaking DeLonghi units specify what the law under TSCA intends, rather than dictates, taking into account the number of units and potential release and exposure to PCBs which may be encountered during the use of these heaters. Likewise, any public notification or supplemental information regarding the handling and disposal of leaking units should clearly specify the recommendations and requirements for disposal at TSCA permitted disposal facilities. OTS expects that the return of leaking units to TSCA permitted disposal facilities will most probably involve retailers or distributors who have received leaking units from consumers returning them under remaining warranty agreements or under DeLonghi replacement agreements with the consumer.

III. Region X Memo Items 4-7 and Miscellaneous Comments.

Item 4 of the Region X memo requested that EPA consider an update to the press release which would better deal with the concerns raised in the Region's memo, particularly disposal issues. OCM does not intend to issue any new or revised press releases at this time. Rather, the issue of public notification regarding disposal will be taken up in the settlement negotiations with DeLonghi.

Item 5 of the Region X memo requested information on the accuracy of certifications from DeLonghi to U.S. Customs. Since the discovery of the problem with DeLonghi, that firm has been required to certify compliance with TSCA in accordance with the regulations promulgated under Section 13. Additionally, the Agency has analyzed 9 samples of oil drawn from DeLonghi heaters. No PCBs were detected in these samples. Future shipments of DeLonghi heaters will also be randomly sampled for compliance.

Item 6 of the Region X memo requested that OCM coordinate efforts with OECM to reach a creative settlement if the pending TSCA administrative action which will ensure the recall of all contaminated heaters, with specific conditions for milestones and penalties. While OCM prefers not to discuss in detail at this time the status of OCM discussions with DeLonghi regarding settlement of the pending TSCA administrative action, OCM will take into consideration Region X's suggestions for a creative settlement.

Item 7 of the Region X memo requested a single point of contact be designated on behalf of headquarters to enhance communication on the DeLonghi situation. This contact is Mr. Mike Hackett, OCM, and he may be reached at (202)382-7835.

On page 3 of the Region X memo, reference is made to the apparent inconsistency between the very high amount of the TSCA penalty assessed in the DeLonghi case in relation to the apparent lack of any other significant action. With respect to this apparent discrepancy (product recall), OCM cites previous TSCA Section 5 actions. Failure to file a PMN for a new chemical can and has resulted in multi-million dollar penalties with no other enforcement actions because, upon further review of the chemical, it was deemed not to present a risk. In some cases the length of time a violation continues has as much to do with the size of the penalty as has the severity of the violation.

The following additional observations are offered for various comments appearing throughout the Region X memo:

Page 1:
Reference is made to the model number on the DeLonghi unit as a possible reference to whether or not the heater may be PCB-contaminated. Information obtained from DeLonghi, and verified by subsequent analysis by EPA, shows that heaters manuafactured after the 21st week in 1986 are PCB free. Accordingly, DeLonghi heaters with serial number 86-21 or higher, e.g., 86-45, 87-2, will not contain PCBs. These serial numbers are found on stickers generally located on the bottom or side panel of these heaters.

Page 3:
Reference is made to the potential conditions for generation of other toxic compounds in the event of a breach of the reservoir were to occur over the heating oils. (The term "thermal weathering", used to describe the condition of the 1 unit examined by Region X, needs to be defined in more specific terms).

The conversion phenomena involved in the formation of polychlorinated dibenzofurans (PCDFs) from PCBs subjected to various elevated temperatures are well documented. Morita et al (1977) reported increasing amounts of PCDFs formed over a 2 week period when PCBs (Aroclor 1248) were heated at 300^0 C in a sealed glass tube, with the reaction catalysed by transition metals or their salts. Morita, Nakagawa and Rappe (1978) conducted heating experiments with Aroclor 1248 to determine conditions, yield and mechanism of reaction involved in these conversions. Their work shows that a minimum temperature of 270^0 C is necessary for tranformation to PCDFs (decomposition occurs at 330^0 C), with oxygen in the PCDF molecule coming from labile oxygen in the reaction. Also, the level of PCDF formation seems to be determined by the transient equilibrium of thermal formation and decomposition, thus defining this critical temperature point of conversion. In their experiments with Yusho oil heated to 300^0 C under oxygen for 1 week, major components of the reaction products were dichloro and trichlorodibenzofurans formed as a result of apparent release of 1 or 2 chlorine atoms (understandable since the starting mixture was primarily Aroclor 1248). The report does mention the possibility of heated metal tubings as possible contributors to reactions for the formation of PCDFs from Yusho oil. In the case of the DeLonghi heaters, however, documented maximum external temperatures reported do not exceed 134^0 C, and maximum internal temperature (actual temperature of oil) is estimated at 200^0 C. Thus, the likelihood of thermal conversion of PCBs to PCDF in the event of a breach of the oil over the heating element is remote.

We hope that the information outlined above will assist you in further understanding the elements of the exposure and risk calculations, the basis for decisions relative to the DeLonghi press release, and the rationale for the actions OTS has taken to date and plans to take in the future on the DeLonghi heater situation.

References:

Morita M., Nakagawa J., Akima K., Mimura S., Isong, N. Detailed Examination of Polychlorinated Dibenzofurans in PCB Preparations and Kanemi Yusho Oil . Bull. Env. Contam. and Tox. Vol. 18, 1977.

Morita M., Nakagawa J., Rappe C. Polychlorinated Dibenzofuran (PCDF) Formation From PCB Mixture by Heat and Oxygen. Bull. Env. Contam. and Tox. Vol. 19, 1978.